**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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| JUAN HUERTAS and EVA MISTRETTA, individually and on behalf of all others similarly situated,<br><br>Plaintiffs,<br><br>v.<br><br>BAYER U.S., LLC,<br><br>Defendant. | Civil Action No: 21-20021 (SDW)(CLW)<br><br>**OPINION**<br><br>August 19, 2022 |

**WIGENTON**, District Judge.

Before this Court is Defendant Bayer, LLC's ("Defendant") Motion to Dismiss, (D.E. 19), Plaintiffs Juan Huertas and Eva Mistretta's (collectively, "Plaintiffs") Class Action Complaint, (D.E. 1), pursuant to Federal Rules of Civil Procedure ("Rule") 12(b)(1) and 12(b)(6). Jurisdiction is proper pursuant to 28 U.S.C. § 1332. Venue is proper pursuant to 28 U.S.C. § 1391. This opinion is issued without oral argument pursuant to Rule 78. For the reasons stated herein, the Motion to Dismiss is **GRANTED**.

## I. BACKGROUND AND PROCEDURAL HISTORY

### A. Facts Underlying the Allegations

Defendant Bayer U.S., LLC is a Delaware corporation, headquartered in Whippany, New Jersey. (D.E. 1 ¶ 34.) Defendant manufactures Lotrimin and Tinactin sprays (the "Products"), which are "anti-fungal drug products regulated by the United States Food & Drug Administration ("FDA")[,] pursuant to the federal Food, Drug[,] and Cosmetics Act ("FDCA")," and sells them

throughout the United States. (*Id.* ¶¶ 1–2.) "Lotrimin is the brand name for Clotrimazole," an antifungal spray or cream that treats various skin infections. (*Id.* ¶ 4.) "Tinactin is the brand name for Tolnaftate," an antifungal spray or cream that treats athlete's foot or ringworm. (*Id.* ¶ 5.)

On October 1, 2021, Bayer announced a voluntary recall of the Products, specifically recalling unexpired "spray products with lot numbers beginning with TN, CV, or NAA, distributed between September 2018 to September 2021," because of "the presence of benzene in some samples of the products." (*Id.* ¶ 11; *see also id.* n.7.) Bayer required consumers seeking a refund to "submit[] proof of purchase" and "submit a picture of the product." (*Id.* ¶ 30.) Bayer also advised consumers not to use the Products and confirmed that "[b]enzene is *not* an ingredient in any of Bayer Consumer Health products." (*Id.* ¶¶ 11–12 (alteration in original).) The level of benzene detected in the affected samples is unknown. (*Id.* ¶ 12.)

In August 2021, Plaintiff Juan Huertas ("Huertas"), a resident of Levittown, New York, "purchased a canister of Defendant's Lotrimin Antifungal (AF) Athlete's Foot Deodorant Powder Spray" with an impacted lot number, from a CVS in New York. (*Id.* ¶ 32.) Huertas reviewed the Product's labels and disclosures, and "used the spray to treat fungal infections on his skin." but did not know the Product contained benzene. (*Id.*) Huertas did not learn of the recall before using the product. (*Id.*)

In July 2021, Plaintiff Eva Mistretta ("Mistretta"), a resident of East Elmhurst, New York, "purchased a canister of Defendant's Tinactin Athlete's Foot Liquid Spray" with an impacted lot number, from a Walgreens in New York. (*Id.* ¶ 33.) Mistretta reviewed the Product's labels and disclosures, and "used the Tinactin to treat fungal infections on her skin," but did not know the Product contained benzene. (*Id.*) Mistretta did not learn of the recall prior to using the product. (*Id.*)

B. Plaintiffs' Allegations

Plaintiffs assert that benzene is "carcinogenic to humans," (*id.* ¶ 7),[1] and that "[t]here is probably no safe level of exposure to benzene," (*id.* ¶ 6).[2] Plaintiffs further contend that "[t]he presence of benzene in the Products renders them adulterated and misbranded," (*id.* ¶ 2), "the presence of benzene in Defendants Products appears to be *the result of contamination*," (*id.* ¶ 12 (alteration in original)), and "any significant detection of benzene in such products is unacceptable," (*id.* ¶ 13). As a result of using the products, Plaintiffs maintain, both Huertas and Mistretta "suffered cellular and genetic injury that creates and/or increases the risk that [they] will [each] develop cancer." (*Id.* ¶¶ 32–33.) Plaintiffs also submit that they and class members "were injured by [losing] the full purchase price of the Products because the Products are worthless, as they are adulterated and contain harmful levels of benzene," (*id.* ¶ 27), and they and class members were injured by "being exposed to high levels of acutely-toxic benzene," (*id.* ¶ 28).

Finally, Plaintiffs seek to represent four potential classes, including (1) a nationwide class of consumers who purchased specific Lotrimin spray products at issue; (2) a nationwide class of consumers who purchased specific Tinactin spray products at issue; (3) a subclass of consumers who purchased the Lotrimin spray products in New York; and (4) a subclass of consumers who purchased the Tinactin spray products in New York. (D.E. 1, ¶¶ 39–42.)

C. Procedural History

On November 16, 2021, Plaintiffs filed a putative class action suit in this Court, asserting the following claims: Breach of Express Warranty (Count I); Breach of Implied Warranty (Count

[1] *Benzene and Cancer Risk*, AM. CANCER SOC'Y (Jan. 5, 2016), https://www.cancer.org/cancer/cancer-causes/benzene.html.

[2] Smith, Martyn T., *Advances in Understanding Benzene Health Effects and Susceptibility*, 31 ANN. REV. OF PUB. HEALTH 133, 133–48 (2010).

II); Violation of New York General Business Law § 349 (Count III); Violation of New York General Business Law § 350 (Count IV); Fraud (Count V); and Unjust Enrichment (Count VI). (*See* D.E. 1 ¶¶ 52–105.) Defendant filed a Motion to Dismiss on January 24, 2022, and the parties completed timely briefing. (*See* D.E. 19, 21, 22.) Defendant submitted supplemental authority to the Court on April 29, 2022, and on July 21, 2022. (*See* D.E. 23, 26.) Plaintiffs did not respond to Defendant's submissions.

## II. LEGAL STANDARD

### A. Rule 12(b)(1) Motion to Dismiss

Subject matter jurisdiction establishes a court's "very power to hear the case." *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). A district court has subject matter jurisdiction to hear claims "arising under the Constitution, laws, or treaties of the United States" pursuant to 28 U.S.C. § 1331. "A motion to dismiss for want of standing is . . . properly brought pursuant to Rule 12(b)(1), because standing is a jurisdictional matter." *Ballentine v. United States*, No. 1999-130, 2006 WL 3298270, at *1 (D.V.I. Sept. 21, 2001), *aff'd and adopted by* 486 F.3d 806, 808–10, 48 V.I. 1059 (3d Cir. 2007). A defendant may move to dismiss a complaint for lack of subject matter jurisdiction under Rule 12(b)(1) by challenging jurisdiction facially or factually. *Const. Party of Pa. v. Aichele*, 757 F.3d 347, 357 (3d Cir. 2014) (citing *In re Schering Plough Corp. Intron/Temodar Consumer Class Action (Schering Plough)*, 678 F.3d 235, 243 (3d Cir. 2012)). "A facial attack 'contests the sufficiency of the complaint because of a defect on its face,' whereas a factual attack 'asserts that the factual underpinnings of the basis for jurisdiction fails to comport with the jurisdictional prerequisites.'" *Halabi v. Fed. Nat'l Mortg. Ass'n*, Civ. No. 17-1712, 2018 WL 706483, at *2 (D.N.J. Feb. 5, 2018) (quoting *Elbeco Inc. v. Nat'l Ret. Fund*, 128 F. Supp. 3d 849, 854 (E.D. Pa. 2015)). "A motion to dismiss for lack of

standing is considered a facial attack. *Schering Plough*, 678 F.3d at 243. "[A] facial attack calls for a district court to apply the same standard of review it would use in considering a motion to dismiss under Rule 12(b)(6), i.e., construing the alleged facts in favor of the nonmoving party." *Const. Party of Pa.*, 757 F.3d at 358 (citing *Schering Plough.*, 678 F.3d at 243)).

Importantly, when a defendant challenges the court's exercise of subject matter jurisdiction, the plaintiff has the burden of proving jurisdiction to survive the motion. *See Dev. Fin. Corp. v. Alpha Hous. & Health Care, Inc.*, 54 F.3d 156, 158 (3d Cir. 1995). Additionally, "[i]n the class action context, the standing inquiry focuses solely on the class representatives." *In re Valsartan, Losartan, and Irbesartan Prods. Liab. Litig.* (*Valsartan II*), No. 2875, 2021 WL 100204, at *5 (D.N.J. Jan. 12, 2021) (citing *Mielo v. Steak'n Shake Operations, Inc.*, 897 F.3d 467, 478 (3d Cir. 2018)).

B. Rule 12(b)(6) Motion to Dismiss

An adequate complaint must be "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). This Rule "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level . . . ." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citing 5 C. WRIGHT & A. MILLER, FEDERAL PRACTICE AND PROCEDURE § 1216, 235–36 (3d ed. 2004)); *see also Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (stating that Rule 8 "requires a 'showing,' rather than a blanket assertion, of an entitlement to relief" (quoting *Twombly*, 550 U.S. at 555)).

When considering a Motion to Dismiss under Rule 12(b)(6), a court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief."

*Phillips*, 515 F.3d at 231 (quoting *Pinker v. Roche Holdings, Ltd.*, 292 F.3d 361, 374 n.7 (3d Cir. 2002)). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 555); *see also Fowler v. UPMC Shadyside*, 578 F.3d 203, 209–11 (3d Cir. 2009) (discussing the *Iqbal* standard). Determining whether the allegations in a complaint are "plausible" is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679 (citation omitted). If "the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct," the complaint should be dismissed for failing to "show[] . . . that the pleader is entitled to relief" as required by Rule 8(a)(2). *Id.*

## III. DISCUSSION

Before addressing whether Plaintiffs' claims are well pleaded, this Court must first consider whether Plaintiffs have standing to pursue the claims. Article III of the United States Constitution limits the power of the federal judiciary to the adjudication of actual "cases" or "controversies." *Golden v. Zwickler*, 394 U.S. 103, 108 (1969); *see also Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 471 (1982). To enforce the "case" or "controversy" requirement, Article III requires that a plaintiff "have 'standing' to invoke the power of a federal court . . . ." *Allen v. Wright*, 468 U.S. 737, 750 (1984). Standing, therefore, is a "threshold question in every federal case, determining the power of the court to entertain the suit." *Warth v. Seldin*, 422 U.S. 490, 498 (1975). A plaintiff has standing to sue when:

> First, the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and

> particularized, and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly . . . trace[able] to the challenged action of the defendant, and not . . . the result [of] the independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

*Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) (internal quotations and citations omitted); *see also Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016).

Here, Plaintiffs allege two separate injuries: economic harm due to the loss of the purchase price of the Products, and physical injury from exposure to benzene via use of the Products. (D.E. 1 ¶¶ 27, 28.) Defendant's challenge to each injury rests squarely on "the '[f]irst and foremost' of the three standing elements, injury in fact." *Cottrell v. Alcon Labs.*, 874 F.3d 154, 162 (3d Cir. 2017) (quoting *Spokeo, Inc.*, 578 U.S. at 338). After assessing Plaintiffs' allegations of economic harm and physical injury, this Court finds that Plaintiffs neither have standing to pursue claims for economic injury related to the loss of the purchase price of the products, nor have standing to pursue claims for physical injury.

A. Economic Harm

Plaintiffs allege that they each suffered economic harm by losing "the full purchase price of the Products because the Products are worthless, as they are adulterated and contain harmful levels of benzene." (*Id.* ¶ 27.) Defendant counters that Plaintiffs cannot establish standing because they could have recouped the amount they paid for the Products, but instead did not accept Defendant's offer of a refund, and, further, Plaintiffs fail to allege that the products did not work as advertised. (D.E. 19-1 at 8–19.)

Defendant's argument that Plaintiffs lack standing because they could have been made whole by accepting the refund offered by Defendant is unavailing. The Third Circuit recently

confirmed that a plaintiff's rejection of a defendant's offer of a refund does not impact standing, stating: "[A]s every first-year law student learns, the recipient's rejection of an offer leaves the matter as if no offer had ever been made." *Adam v. Barone*, 41 F.4th 230, 235 (3d Cir. 2022) (quoting *Campbell-Ewald Co. v. Gomez*, 577 U.S. 153, 162 (2016) (internal quotations omitted)). In this case, Plaintiffs were under no obligation to accept Defendant's offer of a refund. By not participating in the recall program for any reason they may have had for not doing so, and by not taking advantage of the offer of a refund for any reason they may have had for not doing so, Plaintiffs essentially rejected Defendant's offer, and such rejection does not impact standing.

While Plaintiffs' Complaint clears that minimal hurdle, however, it does not sufficiently allege facts that support the conclusion that they suffered economic loss from the Products. To establish an economic loss from a product, a plaintiff "must allege facts that would permit a factfinder to value the purported injury at something more than zero dollars without resorting to mere conjecture." *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Liab. Litig. (Johnson & Johnson)*, 903 F.3d 278, 285 (3d Cir. 2018). A plaintiff may rely on one or more of several different theories of economic loss. *Id.* at 281–83. In this case, Plaintiffs primarily rely on the benefit of the bargain theory. (D.E. 1 ¶ 27.) "Under the benefit of the bargain theory, a plaintiff might successfully plead an economic injury by alleging that [he or] she bargained for a product worth a given value but received a product worth less than that value." *Johnson & Johnson*, 903 F.3d at 283. Several recent cases illustrate how courts analyze similar matters concerning economic loss.

In *Johnson & Johnson*, the plaintiff alleged that she would not have purchased the baby powder product at issue if she had known it was unsafe and may cause health problems. *Johnson & Johnson*, 903 F.3d at 284–90. However, the plaintiff neither alleged facts indicating that she

lost some or all of the value of the product, nor alleged that it did not work as intended. *Id.* The Court found that the plaintiff did not establish economic injury by alleging that she would have bought another product, and instead needed to "allege that she purchased [b]aby [p]owder that was worth less than what she paid for" to establish an injury. *Id.* at 287. The Court additionally found that, despite the product allegedly containing a carcinogen, the plaintiff used the product without cognizable injury, and her "wish to be reimbursed for a functional product that she has already consumed without incident does not itself constitute an economic injury." *Id.* at 293.

In *Cottrell*, the plaintiffs alleged that the design of eye-drop bottles Defendant sold created economic injury due to wasted product that occurred when the drops were more than a person's eye could hold. *Cottrell*, 874 F.3d at 159–60. The Court determined that the plaintiffs had standing because the value of the wasted product was sufficient to constitute a cognizable economic injury. *Id.* at 168.

Here, Plaintiffs allege that they were injured by losing "the full purchase price of the Products because the Products are worthless." (D.E. 1 ¶ 27.) This allegation somewhat aligns with the argument in *Cottrell*, but is distinguishable in that the plaintiffs in *Cottrell* pleaded that they lost money from the amount of product that was wasted when they used the product; here, Plaintiffs do not plead that the Product was wasted or unused in some way, or that they discarded some or all of the Product when they found out about the recall. Plaintiffs also do not plead that the product did not work as advertised. Plaintiffs put forth conclusory assertions that the product is worthless due to the purported benzene contamination but do not set out any facts that demonstrate any actual loss from discarding or sacrificing any portions of the products. As with the plaintiff in *Johnson & Johnson*, Plaintiffs have not presented a particularized account of the actual harm caused, and instead present mere conjecture in asserting that they experienced some

sort of loss due to the product's generally asserted "worthless[ness]," and that some hypothetical, future physical harm may befall them from use of the product. *See Johnson & Johnson*, 903 F.3d at 285. Plaintiffs' claims each amount to a "wish to be reimbursed for a functional product that [they] . . . already consumed without incident," which in and of itself "does not itself constitute an economic injury." *Id.* at 293.

Further, while Plaintiffs contend that the economic standing issue in *Valsartan II* supports standing here, important factual distinctions undercut Plaintiffs' argument. *See Valsartan II*, 2021 WL 100204, at *6–12 (collecting cases). In *Valsartan II*, the plaintiffs alleged that they purchased one or more of Defendant's generic drugs, which were designed to control blood pressure. *Id.* at *1–3. The FDA then discovered that the valsartan-containing drugs ("VCDs") had been contaminated by two probable human carcinogens "—n-nitrosodimethylamine ("NDMA") and n-nitrosodiethylamine ("NDEA")—" and that the amounts of the contaminants exceeded specifically delineated levels acceptable for human ingestion. *Id.* at *1–2. The defendants instituted a voluntary recall, and various plaintiffs sued the manufacturers, arguing that "had they known the product was not the same as the brand-name drug, they would not have paid for it, and had Defendants' deception about the product's impurities been made known earlier, they would not have paid for it." *Id.* at *2. "[C]lasses of consumers and third-party payors [sued] in order to recoup the amounts they paid for Defendants' allegedly worthless VCDs," arguing that "the VCDs were adulterated and misbranded"; "[the consumers] paid to replace the recalled VCDs with substitute drugs, effectively paying twice for drugs intended to treat the same medical conditions and for use over the same (or an overlapping) time period, when they should only have paid once"; and the VCDs "were worth less than their non-contaminated equivalents." *Id.* at *3–4 (internal citations omitted). During the recall, the plaintiffs alleged that they needed to keep taking the

drugs due to the seriousness of the conditions they treated, but then were forced to stop taking the drug due to the seriousness of the impurity and had to purchase non-contaminated drugs as a safe alternative to the contaminated drugs. *Id.* at *4. Considering all of these facts, the District Court found that the plaintiffs had standing to sue for economic injury. *Id.* at *11.

Here, Plaintiffs' allegations have some resemblance to those in *Valsartan II* in that Plaintiffs allege that the Products were worthless due to the presence of a carcinogen contaminant. (D.E. 27.) However, the similarities are limited in that the *Valsartan II* plaintiffs alleged specific high levels of contamination that exceeded the FDA guidelines for the contaminants, and they alleged actual economic harm by having to purchase alternative medications to continue treating their high blood pressure conditions and being forced to stop taking the medications at issue due to the seriousness of the impurity. *Valsartan II*, 2021 WL 100204, at *4. Conversely, Plaintiffs' Complaint does not discuss the actual FDA guidelines or note the specific, acceptable amount of benzene in the given type of product. (D.E. 1 ¶¶ 6, 12.) Further, the Complaint does not allege the specific level of benzene in the impacted Products. (*Id.*) The allegation that "the Products expose consumers to benzene well above the legal limit" is conclusory in that it does not elucidate the actual FDA guideline on the allowable limit, and further fails to compare the allowable amount with the amount that actually existed in the Products—or even allege the amount that existed. (*Id.* ¶ 28.) While Plaintiffs quote a scholarly journal article suggesting that "[t]here is *probably* no safe level of exposure to benzene," that suggestion does not demarcate the requirements that the FDA sets forth concerning levels of carcinogenic contaminants and amounts to probability and speculation. (*Id.* ¶ 6 (emphasis added) (internal citation omitted).)

Plaintiffs further neither allege that they had to stop taking the Products and purchase replacement alternative products, nor allege even throwing the remainder of the Products away, or

whether any amount of the Products even remained after use. (*See id.* ¶¶ 32–33.) While the circumstance in *Valsartan II* is somewhat similar in that impacted products were found to have contaminants, it is not directly analogous to the facts alleged in Plaintiffs' Complaint, and the differences directly impact the standing analysis.

Plaintiffs do not allege that the Products did not work as intended, as discussed in *Johnson & Johnson*; that they suffered wasted portions of the Products by having to discard any or all of them, as discussed in *Cottrell*; or that they purchased a replacement product and effectively paid for the same treatment twice, as transpired in *Valsartan II*; thus Plaintiffs have not demonstrated cognizable economic harm, and their allegation of the "worthless" Products amounts to speculative loss. Viewing the allegations in a light most favorable to Plaintiffs, the facts are not well pleaded and, therefore, Plaintiffs have not established standing due to a cognizable economic injury. Because Plaintiffs have not established the first element of standing relating to injury-in-fact, *see Cottrell*, 874 F.3d at 162, analyses of the causal connection between injury and conduct and the redressability of injury are unnecessary. *Const. Party of Pa.*, 757 F.3d at 361 ("When standing is contested, 'the injury-in-fact element is often determinative.'" (quoting *Schering Plough*, 678 F.3d at 245)).

B. Physical Injury

Plaintiffs' allegations of physical injury boil down to specific claims in the Complaint that plaintiffs "suffered cellular and genetic injury that creates and/or increase the risk that [they] will develop cancer." (D.E. 1 ¶¶ 32–33.) To demonstrate an injury in fact, a plaintiff must show particularization—"it 'must affect the plaintiff in a personal and individual way,'" and concrete injury—it "must be 'de facto'; that is, it must actually exist. *Spokeo, Inc*, 578 U.S. at 339–40 (internal citations omitted). While Plaintiffs allege that they have "suffered cellular and genetic

injury," they give no indication of how that injury came to be, what that injury entails, or how the purported injury does anything other than present a future "risk that [they] will develop cancer." (D.E. 32–33.) Plaintiffs are required to "*show* that his or her injury is 'actual or imminent, not conjectural or hypothetical.'" *Johnson & Johnson*, 903 F.3d at 284 (emphasis added) (quoting *Spokeo, Inc.*, 578 U.S. at 339). Plaintiffs in this case give a conclusory allegation that they have suffered cellular and genetic injuries that increase risk of cancer, but do not give any basis for the allegation, do not *show* how those injuries have occurred, and do not demonstrate that the risk of actual harm is anything other than mere speculation. As such, Plaintiffs have not demonstrated concrete injuries that actually exist, and rather rely on the risk of future harm. Plaintiffs, therefore, have not established standing due to physical injury. Because Plaintiffs have not established the first element of standing relating to injury-in-fact, *see Cottrell*, 874 F.3d at 162, analyses of the causal connection between injury and conduct and the redressability of injury are unnecessary.

Further, because Plaintiffs have not demonstrated standing, this Court cannot address the merits of Plaintiffs' claims. *See Adam*, 41 F.4th at 233 ("[I]f a plaintiff does not have standing, courts 'lack the authority under Article III of the Constitution to consider the merits' of any claim." (quoting *In re Boy Scouts of Am.*, 35 F.4th 149, 156 (3d Cir. 2022)).

## IV. CONCLUSION

For the reasons set forth above, Defendant's Motion to Dismiss is **GRANTED**. Plaintiffs shall have thirty (30) days to file an amended complaint. An appropriate order follows.

/s/ Susan D. Wigenton
**SUSAN D. WIGENTON, U.S.D.J.**

Orig: Clerk
cc: Cathy L. Waldor, U.S.M.J.
Parties